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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,716	01/28/2002	Kenji Asano	0230-0160P	3342
2292 7590 05/04/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER YAO, LEI	
			ART UNIT 1642	PAPER NUMBER
			NOTIFICATION DATE 05/04/2007	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

Application No.

09/856,716

Applicant(s)

ASANO ET AL.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 4 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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***Response to Argument and Amendment***

The Amendment filed on in response to the previous Non-Final Office Action (8/25/2006) is acknowledged and has been entered.

Claim 2 is cancelled. Claims 3 and 4 have been withdrawn for non-elected invention.

Claim 1 has been amended and under consideration.

***The following office action contains NEW GROUNDS of rejection.***

**Rejections Withdrawn**

1. The rejection of claims 1-2 under 35 USC § 112 1<sup>st</sup> paragraph-new matter is withdrawn in view of the amendment to claim 1 and cancellation of the claim 2.
2. The rejection of claims 1 under 35 USC § 102 as being anticipated Arinaga et al., is withdrawn in view of amendment to claim 1.
3. The rejection of claims 1- 2 under 35 USC § 102 as being anticipated by Yamamoto et al., is withdrawn in view of the cancellation of the claim 2 and amendment to claim 1.

**The following is a New Ground of rejection-based the amendment to claims**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquires set forth in *Graham V. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1996), that are applied for establishing a background for determining obviousness under 25 U.S. C. 103 (a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or obviousness

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al., (Biosci Biotechnol Biochem, Vol 61, p 1909-12, 1999, provided in previous office action), in view of Mizoguchi et al., (Gastroenterol Jpn. Vol 22:459-64, 1987).

Claim 1 is drawn to a method for determining whether an extract of *Lentinus edodes* mycelium has a Lymphocyte activated killing (LAK) activity-enhancing effect suitable for a subject comprising the step of isolating lymphocyte fraction, treating the lymphocyte with extract of *Lentinus edodes* mycelium, measuring/comparing the activity of the LAK effect suitable for the subject, wherein the extract of *Lentinus edodes* mycelium is prepared by a method comprising the step of crushing the *lentinus edodes* mycelium in the presence of water and additive enzymes and raise the temperature to inactivate the enzymes.

Yamamoto et al., teach a method of cytotoxicity of lymphocytes, specifically NK cells, induced by a fraction (JLS-18) of extract of *Lentinus edodes* mycelium (LEM). Yamamoto et al., teach method steps, preparing NK lymphocytes, and measuring and comparing the LAK activity of NK cell treated with the fraction of LEM (page 1909-10, section materials and result). Yamamoto et al., teach that extract of LEM has a LAK activity-enhancing effect and the LAK activity is increased further by fractions of extract of LEM (page 1910-1911, and figure 1).

Yamamoto et al., do not teach that extract of LEM is prepared by the method steps comprising in the presence of one or more enzyme and raising the temperature of said suspension to inactivate the enzymes.

However, Mizoguchi et al., teach a method of preparation of LEM comprising LEM are crushed and delignified in a solid medium composed of sugar-cane bagasse and defatted rice bran, mycelia enzyme for digestion is added, and finally extract of LEM were filtered and lyophilized for use (Page 628).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Yamamoto et al., with the teaching of Mizoguchi et al., in order to use LEM to enhancing the LAK activity for treating a tumor or infection because Yamamoto et al., teach a

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immunopotentiating activity of the fraction of LEM for the NK cells (last line of abstract). Based on the teaching of Mizoguchi et al., one of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success to make the extract of LEM by adding final step of raising the temperature to inactivate the enzyme because inactivation of the digested enzyme is necessary step known by one skilled in the art. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining the teachings of Yamamoto et al., with the teaching of Mizoguchi et al., because Yamamoto et al., have shown the all method steps of determining LAK activity-enhancing effect by fraction of LEM and Mizoguchi et al., have shown a basic method of preparation of extract of LEM. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

#### Response to applicant's argument

The response filed 1/25/2007 has been carefully considered but is deemed not to be persuasive. Applicant argues that Yamamoto et al., only disclose that the extract of the reference has an effect on activating NK cells, does not contain only any description as to whether the extract enhance LAK activity and present invention can enhance LAK activity both in vivo and in vitro. In response to this argument, first, Yamamoto et al., teach enhanced cytotoxicity of NK cells treated with fraction of LEM compared to the control (figure 1 and legend). NK cell cytotoxicity assay is a well-known assay in the art. Because NK cells as isolated from a subject without treatment in vivo have base line of cytotoxicity for the target cells. Stating activating NK cytotoxicity is the same meaning of enhancing the LAK (lymphokine-activated killer) since the claimed method step does not comprise the lymphokine treatment, such as IL-2, as the claimed invention. Thus, Yamamoto et al., teach the same materials, cells, and method step, which would have the same result. Second, regarding to the argument of enhancing LAK activity in vivo, claimed invention are drawn to in vitro method of determining the LAK activity the preamble language "LAK activity-enhancing effect suitable for a subject" is not given patentable weight because it does not recite an active step of the claims and as sated above, Yamamoto et al., teach the same materials, cells, and method

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step, which would have the same effect suitable for a subject. Thus, Applicant's argument for the teaching of Yamomoto has not been found persuasive.

**Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.


Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao,  
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Art Unit 1642

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